

## REMARKS

In the Office Action dated November 18, 2002, the Examiner has set forth a requirement for restriction under 35 U.S.C. §§121 and 372, alleging that the subject matter defined by the claims of the present invention represents the following two separate and distinct inventions which do not relate to a single general inventive concept under PCT Rule 13.1:

- I. Claims 1-13, 17, 18, 27, 28, 34-38, 40, 43 and 47, drawn to a method of repressing, delaying or otherwise reducing expression of a target gene in an animal cell, wherein said target gene is endogenous to the animal cell.
- II. Claims 1-11, 14-33, 36-39 and 41-47, drawn to a method of repressing, delaying or otherwise reducing expression of a target gene in an animal cell, wherein said target gene is derived from the genome of a pathogen.

In accordance with 37 CFR §1.499, Applicants are required to elect a single invention to which the claims must be restricted. The Examiner further states that claims 2-11, 17, 18, 27, 28, 36-38, 43 and 47 embrace both Groups I and II and will therefore be examined only to the extent that they read on the elected subject matter.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Claims 1-13, 17, 18, 27, 28, 34-38, 40, 43 and 47, drawn to a method of repressing, delaying or otherwise reducing expression of a target gene in an animal cell, wherein said target gene is endogenous to the animal cell. Applicants reserve the right to file a divisional application directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

The Examiner alleges that the inventions listed as Groups I-II do not relate to a single

general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The Examiner acknowledges that Groups I and II are united in that they both comprise the special technical feature of introduction of nucleic acid molecules comprising tandem copies of a nucleotide sequence identical to or complementary to the nucleotide sequence of a target gene. However, the Examiner alleges that suppression of target gene expression by introduction of nucleic acid molecules comprising tandem copies of a nucleotide sequence identical to or complementary to the nucleotide sequence of a target gene was known in the art at the time the instant application was filed, as evidenced by the International Search Report mailed 10 May 1999. The Examiner reasons that, as the method of suppressing target gene expression does not represent a contribution over the prior art, the claims of Group I lack a special technical feature that is the same as or that corresponds to a special technical feature of Group II. Therefore, the Examiner concludes that there is no special technical feature linking the recited Groups, as would be necessary to fulfill the requirement for unity of invention.

It is not clear to Applicants as to which reference(s) the Examiner is referring to as allegedly providing a teaching for a method of suppressing target gene expression by introduction of nucleic acid molecules comprising tandem copies of a nucleotide sequence that is identical or complementary to the nucleotide sequence of a target gene. In any event, Applicants respectfully submit that no prior art teaches suppression of target gene expression in animal cells by introducing tandem copies of a nucleotide sequence that is identical or complementary to, or substantially identical or complementary to, the nucleotide sequence of a target gene. Therefore, Applicants submit that Groups I and II both comprise introduction of nucleic acid molecules comprising tandem copies of a nucleotide sequence substantially identical or complementary to

the nucleotide sequence of a target gene in order to suppress target gene expression in animal cells, which is a special technical feature of the present invention and is patentably distinct over the prior art. Therefore, Applicants respectfully submit that Groups I and II share a special technical feature and relate to a single general inventive concept.

The Examiner further alleges that the method of Group I, directed to suppression of endogenous genes within an animal cell, differs in both function and effect from the method of Group II, which is directed to suppression of genes comprised within the genome of a pathogenic organism. For example, the function and effect of the method of Group I could be to suppress neoplastic cell growth by inhibiting expression of an oncogene, while the function and effect of the method of Group II is limited to inhibiting expansion or toxicity of a pathogen.

Applicants respectfully disagree with the Examiner. It is submitted that a principal feature of the claimed invention resides in the recognition that suppression of gene expression of a target gene can be achieved in an animal cell by introduction into the animal cell tandem copies of a nucleotide sequence that is substantially identical to or complementary to the nucleotide sequence of a target gene, regardless of whether the target gene is an endogenous gene within the animal cell or a gene within the genome of a pathogenic organism. Therefore, Applicants respectfully submit that, contrary to the Examiner's allegations, the method of Group I where the target gene is an endogenous gene within an animal cell, and the method of Group II where the target gene is a gene within the genome of a pathogenic organism, are directed toward achieving the same function and effect – i.e., suppression of the target gene expression in the animal cell.

Furthermore, Applicants respectfully submit that the method of Group I and the method of Group II are believed to be achieved by essentially the same mechanism. As described at page 17, lines 9-14 of the specification, the reduced or eliminated expression of the

target gene which results from the performance of the invention may be attributed to reduced or delayed translation of the mRNA transcription product of the target gene or alternatively, the prevention of translation of the mRNA, as a consequence of sequence-specific degradation of the mRNA transcript of the target gene by an endogenous host cell system (i.e., a system within the animal cell).

Therefore, Applicants respectfully submit that Group I and Group II are clearly linked to each under a single inventive concept and are merely different aspects of a single invention. The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle

GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the defined two groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Frank S. DiGiglio  
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343  
FSD/XZ:ab